

REMARKS

Claims 1-3, 5-8, 10-13, 29-32, 45-48, and 50-72 are pending in the application. The numbered paragraphs below correspond to the Examiner's numbered paragraphs:

1. Applicant acknowledges the acceptance of the RCE.
2. Applicant acknowledges the removal of the 35 U.S.C. § 112 rejections based on Applicant's remarks.
3. Claims 1-3, 5, 45, 47, 48, 50, 64-66, and 70-72 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Dang et al. (U.S. Patent No. 6,758,859) ("Dang"). Applicant respectfully traverses on the following grounds:

A. The Examiner has indicated that col. 4, lines 17-40 teach the claimed element of the second material which is configured to convert a first type of energy to a second type of energy. Col. 4, lines 17-40 teach materials from which a stent body can be made, including for example gold, and **not** materials that are deposited **into depots of the stent body**, as claimed.

B. As correctly indicated by the Examiner, col. 5, lines 54-56 do teach that radioactive isotopes could be deposited in the depots of the Dang stent. However, such teaching is well short of what has been claimed. **Dang fails to teach that the radioactive isotopes are used with the therapeutic substance. To the contrary, the reference, as a whole, teaches that the radioactive isotopes are an alternative form of therapy that can be substituted with the therapeutic substance and not used in combination.** For example, the second and third paragraphs of col. 6 teach that the **depots have to be of a first size to accommodate the drug**

and a second size to accommodate the radioactive isotopes. Moreover, it is clearly apparent to one having ordinary skill in the art that combining a radioactive isotope with a therapeutic substance may lead to degradation of the substance. Therefore it would be counterintuitive to combine the two. Nowhere in Dang is the concomitant combination of a drug and radioactive material disclosed. Accordingly, the reference fails to teach “a first material including a therapeutic substance; an a second material configured to convert a first type of energy received by the second material from an energy source to a second type of energy, wherein the second type of energy promotes release of the therapeutic substance from the first material, and wherein the second material is in the depots of the stent body,” as recited by claim 1.

C. Assuming, for the sake of argument, that Dang does in fact teach the combination of using a drug and a radioactive agent at the same time, Applicant respectfully submits that this teaching would still fall short of what has been claimed. In other words, the size of the radioactive material, the shape of the material, or the number or amount of the material could be well short of being capable of promoting the release a therapeutic substance. Moreover, the positioning of the Dang radioactive material could be such as to not be able to promote the release of the therapeutic substance. Dang is simply not enabling with respect to these issues. The Examiner is making a tenuous leap and many conjectures about the teachings of Dang that fall well short of what has been claimed. In sum, even if both a drug and a radioactive isotope are used at the same time (which Dang clearly states that they are not), this does not mean that the “second material [is] configured to convert a first type of energy received by the second material from an energy source to a second type of energy, wherein the **second type of energy promotes release of the therapeutic substance from the first material.**”

Based on the above three points, Applicant respectfully believes that independent claims 1 and 45 are patentably allowable over Dang. Claims 2, 3, 5, 47, 48, 50, 64, 65, 66, 70, 71 and 72 depend from claims 1 or 45 and are allowable for at least the same reason.

With respect to claim 64, claim 62 from which claim 64 depends has been allowed, but for the claim being in dependent form. Applicant respectfully fails to see how claim 64 can be rejected, since it includes the limitations of claim 62. Similarly, claim 70 is dependent from allowed claim 68, but has been rejected as well. Clarification of these two rejections is respectfully requested.

D. The Examiner has indicated that Figure 4 of Dang teaches a topcoat. **Nowhere in Dang is a topcoat described.** As indicated by the Brief Description of the Drawings, Figure 4 illustrates a portion of an implantable device having depots on the surface of the device. The depots are clearly shown by circles 30. Applicant respectfully fails to see how the Examiner could reasonably contend that Figure 4 shows a topcoat. There are absolutely no markings of any sort to indicate that Figure 4 of Dang includes a topcoat. If a topcoat was included in the figure, one would assume the specification would have some kind of description, no matter how brief and the figure would have some kind of depiction or reference number, no matter how non-illustrative. Furthermore, if a topcoat was depicted by Figure 4, one would think that the depots 30 would be covered by the topcoat and not illustrated -- yet all the depots 30 remain clearly illustrated.

4. Claims 6, 11-13, 31, 32, 51, 56-61 and 67 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Dang.

A. The Examiner is contending that even though Dang is silent regarding the use of Au particles having silica nano-particle core or a temperature sensitive hydrogel material, it would have been obvious to one having ordinary skill in the art, at the time of the invention, to use such particles and materials. In support of this position, the Examiner has cited In re Leshin, 125 USPQ 416. Applicant respectfully disagrees with the Examiner's position.

First, **Dang simply fails to teach the use of any kind of particles**. If Dang fails to teach particles, then it is certainly not obvious to one having skill in the art to select gold as the particle of choice. Dang uses gold to form the body of the stent and radioactive isotopes as fillers for the depots. Nowhere in Dang is the use of particles disclosed.

Second, the mode of drug release of Dang -- namely, simple release action of a drug out from stent depots, is vastly different than the "pump" release action of the present invention. The Applicant respectfully submits that the Examiner's contention, that it would be obvious to use the material of Dang with the mechanism of the present invention, is technically without merit since modes of action are vastly different.

Third, Applicant respectfully submits that the facts of In re Leshin are vastly different from what has been presented in the application at bar. Claim 13 of Leshin, which was in dispute, did not recite any kind of material. The court held that because "the material of which the device is made is not specified [by claim 13], patentability of the claim cannot be predicted on the use of plastics." With respect to the dependent claims that did recite plastics, Applicant believes that the prior art reference of In re Leshin disclosed similar containers for similar use. In contrast, Dang teaches gold to make the body of the stent. It does not teach gold in particle form as a means to deliver a drug. The Examiner is taking a material for one purpose and is suggesting that its use for a completely and vastly different purpose is obvious. Under the

Examiner's standard, all new uses for an old material would be considered obvious. The case law is very clear on this issue, that the use of an old material for a new purpose is patentable. Moreover, Applicant has failed to find any reference to a hydrogel material in the Dang reference. Accordingly, unlike In re Leshin where a similar material was disclosed for similar purpose, Dang does not teach any similar material used for a similar purpose.

B. With respect to claims 29, 30, 52 and 53, it is the Examiner's position that even though Dang is silent regarding the diameter of the Au particles, since Dang discloses Au particles, change in size would be routine to one skilled in the art.

First, as indicated above, Dang does not teach Au particles. In fact, Dang does not teach any kind of particles. Dang teaches that the stent struts or stent body can be laser cut from gold. Gold aside, even with respect to the radioactive isotopes, **Dang fails to teach that these isotopes can be in particle form.**

Second, as indicated in the specification, size and thickness have an integral role in peak absorbance and thermal output energy, among other factors. Accordingly, size and thickness adjustment play an important factor that goes beyond simple, routine experimentation. The Examiner should not trivialize this size selection as routine experimentation. Third, regardless of the above points, claims 29, 30, 52, and 53 depend on claims 1 or 45 and are patentably allowable for at least the same reasons.


5. Claims 7, 8, 54, 55, 62, 63, 64, 68, 69 and 70 have been allowed but for being based on a rejected base claim. Claims 7, 54 and 62 have been placed in independent form. Claims 8, 55, 63, 64, 68, 69, and 70 depend from claims 7, 54, or 62.

CONCLUSION

Applicant respectfully submits that the claims have been placed in condition for allowance. Removal of all rejections is respectfully requested. Applicant respectfully requests the Examiner to enter the foregoing amendments and pass the case to issue.

If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0345.

Respectfully submitted,


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